27 and 28 under 35 U.S.C. §103. Claims 11-22 have been canceled; and Claims 30-41 have been newly added. Attached hereto is a marked up version of the changes made by the current amendment. The attached page is captioned "**Versions with Markings to Show Changes Made.**" Applicants respectfully submit that the rejections have been overcome in view of the amendments and/or for the reasons set forth below.

In the Office Action, Claims 11-22 and 27-29 are rejected under 35 U.S.C. §112, first paragraph. The Examiner alleges that the claimed subject matter was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Applicants respectfully submit that this rejection is improper. At the outset, Claims 11-22 have been canceled thus rendering moot this rejection with respect to Claims 11-22. With respect to Claims 27-29 and newly added Claims 30-41, Applicants believe that that the claimed subject matter is sufficiently described in the specification so as to enable one skilled in the art to make and/or use same.

Independent Claim 27 recites a method for enhancing the recovery of a damaged organ that includes, in part, administering a composition including a dietary protein that increases the protein concentration or synthesis in the organ. Newly added independent Claim 30 recites a method for promoting growth or recovery of a specific organ of a mammal as determined by a measurable indicator which can include weight, protein concentration, RNA concentration, protein synthesis capacity, protein synthesis rate, daily protein synthesis, ribosomal activity and combinations thereof of the specific organ as further recited in newly added Claim 31.

As demonstrated on the Table on page 22 of Applicants' specification, for example, the protein synthesis rate in the duodenum is significantly increased if rats are fed with feed made pursuant to an embodiment of the present invention. Further, it is generally known and understood that measurable indicators, such as protein synthesis rate, are generally regarded as reliable indicators for growth or general recovery. Therefore, Applicants believe that one skilled in the art would clearly understand that by selecting a specific dietary protein for a specific organ, recovery can be promoted as determined by one or more of the measurable indicators as required by the claimed invention. Thus, Applicants believe that the claimed invention fully complies with 35 U.S.C. §112, first paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 11-22 are rejected under 35 U.S.C. §112, second paragraph. At the outset, Claims 11-22 have been canceled as previously discussed thus rendering moot this rejection. Moreover, Applicants believe that the pending claims fully comply with 35 U.S.C. §112, paragraph two.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 11, 13, 17, 19, 21, 23, 25 , 26 , 27 and 28 are rejected under 35 U.S.C. §103 as allegedly being unpatentable over U.S. Patent No. 5,679,771 ("*Ballard*"). The Examiner appears to suggest that the insulin-like growth factor -I("IGF-I") of *Ballard* can be obviously modified to arrive at the claimed invention.

Applicants respectfully submit that this rejection is improper. At the outset, Claims 11-22 have been canceled thus rendering moot the obviousness rejection with respect to these claims. Of the pending claims, Claims 23, 27 and 30 are the sole independent claims. Claim 23 recites a method of enhancing the growth of a selected organ in a patient including the steps of administering a composition including a dietary protein that increases protein concentration or synthesis in the selected organ wherein the dietary protein includes a protein hydrolysate, free amino acids or mixtures thereof. Claim 27 recites a method for enhancing the recovery of a damaged organ that includes impart, the steps of administering a composition including a dietary protein that increases protein concentration or synthesis in the organ. Claim 30 requires a method for promoting growth or recovery of a specific organ including a small intestine, a duodenum, a jejunum, a liver and a skeleton muscle of a mammal as determined by a measurable indicator. The method includes selecting a dietary protein that includes a protein hydrolysate having a specific degree of hydrolysis, one or more free amino acids or mixtures thereof; and administering a therapeutically effective amount of the dietary protein to the mammal.

Applicants have discovered that the selected use of a specific dietary protein can be used to target specific organs to promote recovery or growth of same as measured by an indicator including, for example, weight, protein synthesis, protein concentration and/or the like. For example, Applicants have demonstrated that the protein synthesis rate in the duodenum can be significantly increased if rats are fed with feed made pursuant to an embodiment of the present invention. In particular, this demonstrates that the feed made pursuant to an embodiment of the present invention that contains a protein hydrolysate having a degree of hydrolysis of about 35%

has an enhanced effect on the protein synthesis rate which is generally understood to be an indication for growth or recovery. See, the Specification, for example, pages 9-22.

Applicants believe that the dietary protein including, for example, protein hydrolysates that have a higher degree of hydrolysis are rapidly digested and absorbed in the upper small intestine. In this regard, a protein substrate can be available for protein synthesis in the upper small intestine such that the upper small intestine may be targeted.

Further, intact protein and protein hydrolysate that have a lower degree of hydrolysis, for example, can take longer to digest and are more slowly absorbed in the lower small intestine. In this regard, a protein substrate can be available for protein synthesis in the lower small intestine. Also, the lower rate of absorption may result in more protein substrate being available for protein synthesis in the muscles due to the decrease in liver oxidation such that the lower small intestine and muscles may be targeted. See, Specification, pages 2-3.

In contrast, Applicants believe that the cited reference fails to teach or suggest a number of features of the claimed invention. At the outset, the clear focus of the cited reference is to use IGF-I to treat disorders in gut function in mammals. See, *Ballard*, column 2, lines 3-5. In this regard, nowhere does the cited reference teach or suggest that a selected dietary protein, such as a protein hydrolysate with a specific degree of hydrolysis, can be used to target specific organs of a mammal allowing enhanced growth or recovery as measured by, for example, weight, protein synthesis, protein concentration, other suitable indicators and combinations thereof as required by the claimed invention. *Ballard* merely discloses the alleged treatment of intestinal diseases in general and thus fails to teach or suggest the targeted use of IGF-I, let alone the specific dietary proteins of the claimed invention, such as a protein hydrolysate with a specific degree of hydrolysis, for enhancing growth or recovery of specific organs of a mammal. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify the IGF-I dietary agent and related teachings of *Ballard* to arrive at the claimed invention.

Based on the apparent differences between the cited reference and the claimed invention, Applicants believe that the cited reference fails to teach or suggest a number of features of the claimed invention. Therefore, Applicants respectfully submit that the cited reference fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in a condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel Claims 11-22 without prejudice and disclaimer.

Claims 30-41 have been added as follows:

30. A method for promoting growth or recovery of a specific organ selected from the group consisting of a small intestine, a duodenum, a jejunum, a liver and a skeleton muscle of a mammal as determined by a measurable indicator, the method comprising the steps of:

selecting a dietary protein selected from the group consisting of a protein hydrolysate having a specific degree of hydrolysis, one or more free amino acids and mixtures thereof; and

administering a therapeutically effective amount of the dietary protein to the mammal.

31. The method of Claim 30 wherein the measurable indicator is selected from the group consisting of weight, protein concentration, RNA concentration, protein synthesis capacity, protein synthesis rate, daily protein synthesis, ribosomal activity and combinations thereof of the specific organ.

32. The method of Claim 30 wherein the specific organ is the small intestine and the dietary protein is the protein hydrolysate with the degree of hydrolysis of at least 30%.

33. The method of Claim 30 wherein the specific organ is the duodenum and wherein the protein hydrolysate comprises more than about 30% by weight of di- and tri-peptides and has a non protein nitrogen concentration of about 85% or more of total nitrogen.

34. The method of Claim 30 wherein the specific organ is the jejunum and the protein hydrolysate has the degree of hydrolysis of about 15% or more.

35. The method of Claim 34 wherein the dietary protein is the protein hydrolysate comprising more than about 20% by weight of a di- and tri-peptides and a non protein nitrogen concentration of about 60% or more of total nitrogen.

36. The method of Claim 30 wherein the specific organ is the skeleton muscle and the dietary protein is in the form of one or more of the free amino acids.

37. The method of Claim 36 wherein the mammal is suffering from muscular atrophy.

38. The method of Claim 36 wherein the mammal is suffering from a compromised gut function.

39. The method of Claim 30 wherein the dietary protein is provided in a nutritional formula.

40. The method of Claim 39 wherein the dietary protein is a protein hydrolysate acceptable for premature babies having underdeveloped intestines.

41. The method of Claim 40 wherein the protein hydrolysate comprises more than about 30% by weight of di- and tri-peptides and has a non protein nitrogen concentration of about 85% or more of total nitrogen.